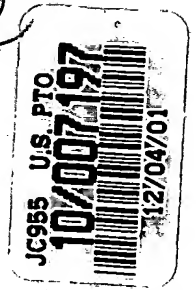


IN THE UNITED STATES PATENT AND TRADEMARK OFFICE



Applicants: James Ronald Lawter and Stephen J. Comiskey

Serial No.: Continuation of 09/661,836 Art Unit: Not Yet Assigned

Filed: December 4, 2001 Examiner: Not Yet Assigned

For: *FORMULATIONS FOR TREATING OR PREVENTING MUCOSITIS*

BOX PATENT APPLICATION
U.S. Patent and Trademark Office
P.O. Box 2327
Arlington, VA 22202

INFORMATION DISCLOSURE STATEMENT

Sir:

Pursuant to 37 C.F.R. §1.56 and 37 C.F.R. §1.97, Applicants submit an Information Disclosure Statement, including four (4) pages of Form PTO-1449. The documents cited below were cited by or submitted to the Patent Office in Application Serial No. 09/661,836, filed September 14, 2000, to which the present application claims priority. Pursuant to 37 C.F.R. §1.98(d), Applicants are not enclosing copies of these publications. Copies will be provided upon request, however.

This Information Disclosure Statement is being filed under 37 C.F.R. § 1.97(b) prior to a first Office Action on the merits. It is believed that no fee is required with this submission. However, should a fee be required, the Commissioner is hereby authorized to charge any required fees to Deposit Account No. 50-1868.

U.S. Patents

<u>Number</u>	<u>Issue Date</u>	<u>Patentee</u>	<u>Class/Subclass</u>
3,966,808	06-29-1976	Luciano	260/559
4,961,926	10-09-1990	Gabrilove	424/85.1
5,082,653	01-21-1992	Pan et al.	424/54
5,102,870	04-07-1992	Florine et al.	514/12
5,284,963	02-08-1994	Sum et al.	552/205
5,328,902	07-12-1994	Sum et al.	514/152
5,386,041	01-31-1995	Sum et al.	552/205
5,401,729	03-28-1995	Sum et al.	514/152
5,420,272	05-30-1995	Sum et al.	544/63
5,430,162	07-04-1995	Sum et al.	552/205
5,545,668	08-13-1996	Skubitz et al.	514/561
5,635,489	06-03-1997	Haley	514/21
5,827,840	10-27-1998	Ramamurthy et al.	514/152
5,886,175	03-23-1999	Sum et al.	544/63
5,945,089	08-31-1999	Libin	424/54
5,981,499	11-09-1999	Hau	514/29
6,025,326	02-15-2000	Steinberg et al.	514/2

Foreign Documents

<u>Number</u>	<u>Publication Date</u>	<u>Patentee</u>	<u>Country</u>
WO 94/27579 A1	12-08-1994	Ribogene, Inc.	PCT
WO 98/18610 A1	05-07-1998	Bernard Van Lengerich	PCT
WO 99/22703 A1	05-14-1999	Lurident Ltd.	PCT
WO 99/45910 A2	09-16-1999	Mucosal Therapeutics LLC	PCT
WO 00/07601 A1	02-17-2000	Advanced Vision Research	PCT

Publications

BARKER, et al., "Oral care with vancomycin paste for reduction in incidence of alpha-hemolytic streptococcal sepsis," *J Pediatr Hematol Oncol* 17(2):151-55 (1995).

CARTEE, et al., "Evaluation of GM-CSF mouthwash for prevention of chemotherapy-induced mucositis: a randomized, double-blind, dose-ranging study," *Cytokine* 7(5):471-7 (1994).

CHI, et al., "Effect of granulocyte-macrophage colony-stimulating factor on oral mucositis in head and neck cancer patients after cisplatin, fluorouracil, and leucovorin chemotherapy," *J. Clin. Oncol.* 13(10):2620-28 (1995).

CUTLER & SCHUBERT, "Patient factors affecting *Helicobacter pylori* eradication with triple therapy," *American Journal of Gastroenterology* 88(4):505-509 (1993).

EPSTEIN & WONG, "The efficacy of sucralfate suspension in the prevention of oral mucositis due to radiation therapy," *Int. J. Radiat. Oncol. Biol. Phys.* 28(3):693-98 (1994).

EPSTEIN, et al., "Benzylamine hydrochloride in prevention and management of pain in oral mucositis associated with radiation therapy," *Oral Surg. Oral Med. Oral Pathol.* 62(2):145-8 (1986).

EPSTEIN, et al., "Prevention of oral mucositis in radiation therapy: a controlled study with benzylamine hydrochloride rinse," *Int. J. Radiation Oncology Biol. Phys.* 16(6):1571-5 (1989).

Essentials of Medicinal Chemistry John Wiley and Sons, Inc., pp 512-517 (1976).

FACCHINI, et al., "Attività di flunoxapofene per uso topico nelle vaginiti aspecifiche. Confronto con meclociclina solfosalicilato," *Minerva Ginecologica* 41(12):609-614 (1989).

FERRETTI, et al., "Control of oral mucositis and candidiasis in marrow transplantation: a prospective, double-blind trial of chlorhexidine digluconate oral rinse," *Bone Marrow Transplant* 3(5):483-93 (1990).

FOOTE, et al., "Randomized trial of a chlorhexidine mouthwash for alleviation of radiation-induced mucositis," *J. Clin Oncol.* 12(12):2630-33 (1994).

FRANCESCHI, et al., "Solitary J-pouch ulcer causing pouchitis-like syndrome," *Diseases of the Colon and Rectum* 29(8):515-517 (1986).

LOPRINZI, et al., "Alleviation of cytotoxic therapy-induced normal tissue damage," *Sem. Oncol.* 22(2) Suppl. 3:95-97 (1995).

MITSCHER, et al., "Quinolone antimicrobial agents. 1. Versatile new synthesis of 1-alkyl-1,4-dihydro-4-oxo-3-quinolinecarboxylic acids," *J. Med. Chem.* 21(5):485-9 (1978).

ROTHWELL & SPEKTOR, "Palliation of radiation-related mucositis," *Special Care in Dentistry* 10(1):21-25 (1990).

SCHENK, et al., "Controlled local delivery of tetracycline HCl in the treatment of periimplant mucosal hyperplasia and mucositis," *Clinical Oral Implants Research* 8(5):427-433 (1997).

SONIS, 1993b, "Oral Complications in Cancer Therapy," In: *Principles and Practice of Oncology*, De Vitta et al., eds., pp. 2385-2394 (J. B. Lippincott, Philadelphia).

Special Care in Dentistry Jan.-Feb, pages 21-25 (1990).

SPIJKERVET, et al., "Chlorhexidine inactivation by saliva," *Oral Surg. Oral Med. Oral Pathol.* 69(4):444-49 (1990).

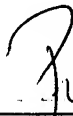
VERDI, et al., "A double-blind, randomized, placebo-controlled, crossover trial of pentoxifylline for the prevention of chemotherapy-induced oral mucositis," *Oral Surg. Oral Med. Oral Pathol. Oral Radiol. Endod.* 80(1):36-42 (1995).

WEISDORF, et al., "Oropharyngeal mucositis complicating bone marrow transplantation: prognostic factors and the effect of chlorhexidine mouth rinse," *Bone Marrow Transplant* 4(1):89-95 (1989).

Remarks

This statement should not be interpreted as a representation that an exhaustive search has been conducted or that no better art exists. Moreover, Applicants invite the Examiner to make an independent evaluation of the cited art to determine its relevance to the subject matter of the present application. Applicants are of the opinion that their claims patentably distinguish over the art referred to herein, either alone or in combination.

Respectfully submitted,



Patrea L. Pabst
Reg. No. 31,284

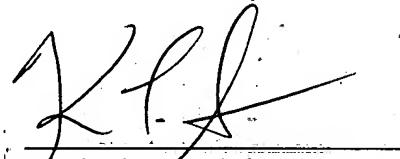
Dated: December 4, 2001
HOLLAND & KNIGHT LLP
One Atlantic Center
1201 West Peachtree Street, N.E.
Suite 2000
Atlanta, Georgia 30309-3400
404-817-8500
FAX 404-817-0470
www.hklaw.com

Continuation of U.S.S.N. 09/661,836
Filed: December 4, 2001
INFORMATION DISCLOSURE STATEMENT
Express Mail Label No.: EL 639 985 041 US
Date of Deposit: December 4, 2001

CERTIFICATE OF MAILING UNDER 37 C.F.R. § 1.10

I hereby certify that this paper and any documents referred to as attached or enclosed are being deposited with the United States Postal Service on this date, December 4, 2001, in an envelope as "Express Mail Post Office to Addressee" service under 37 C.F.R. § 1.10, Express Mail Label No. EL 639 985 041 US, addressed to Box Patent Application, U.S. Patent and Trademark Office, P.O. Box 2327, Arlington, VA 22202.

Date: December 4, 2001



Kimberly L. Adams

ATL1 #495265 v1